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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/096,832	06/12/98	WACHTER E	PHO-104

EXAMINER	
RAM, I	
ART UNIT	PAPER NUMBER
3739	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/096,832	WACHTER ET AL.
	Examiner	Art Unit
	Jocelyn D Ram	3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-142* is/are pending in the application.

4a) Of the above claim(s) *117-131,136-138 and 142* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-116,132-135 and 139-141* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2-4* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-116, 132-135 and 139-141 drawn to a method of treating a tissue with at least one photo-active agent and then treating the tissue with light to promote multi-photon activation, classified in class 128, subclass 898.

II. Claims 117-131, 136-138 and 142 drawn to an apparatus comprising a light source and a focusing apparatus, classified in class 607, subclass 89.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used for any type of laser surgery, for example cataract surgery.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification. restriction for examination purposes as indicated is proper.

During a telephone conversation with Mark Murphy on February 29, 2000 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-116, 132-135 and 139-141. (Note: The assertion made in the letter dated Dec 22, 2000, that Group I should include claims 132-135 and 139-141 in addition to the originally stated claims 1-116, has been affirmed by the examiner.) Affirmation of this election must be made by applicant in replying to this Office action. Claims 117-131, 136-138 and 142 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-33 and 73-106 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-68 of U.S. Patent No. 5,829,448. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention encompasses the patented invention. Multi-photon excitation includes simultaneous two-photon excitation.

Claims 34-106 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 5,998,597. Although the conflicting claims are not exactly identical, they are not patentably distinct from each other because all of the same elements are claimed except for replacing simultaneous two-photon excitation with multi-photon excitation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25, 64, 101 and 107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 25, 64 and 101, it is unclear what the definition of a "photophysical" process is. Claim 107 states that "at

least one photo-active agent...is excited", however it appears that the photons in the photo-active agent are actually being excited.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6, 7, 8, 16-19, 22, 27, 28, 30, 31, 33-39, 42, 45-48, 56-58, 61, 65-67, 69, 70, 132 and 133 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawai et al. (4,822,335). Kawai et al. show a method for treating a tissue comprising: treating the tissue with at least one photo-active agent (col 3, lines 19-28); and treating the tissue with light to promote a multi-photon photo-activation of at least one photo-active agent in the tissue (col 3, lines 29-50); wherein the light is a laser (col 3, line 33); the wavelength is preferably 630-690 nm; and the agent can be a hematoporphyrin derivative.

In US Patent No. 5,829,448 (and subsequent applications), the applicant argued that the distinct difference between the instant invention and the Kawai et al. reference was the **simultaneous** photon excitation. However, this distinction has been removed from many of the claims of the instant application.

Allowable Subject Matter

Claims 107-116 and 135 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. 112, second paragraph, set forth in this Office action.

The following is a statement of reasons for the indication of allowable subject matter: The prior art of record fails to show a method of treating tissue including at least one photoactive agent comprising: illuminating tissue to cause multi-photon excitation of at least one photoactive agent; wherein said photons in at least one photoactive agent are first excited to a transient virtual state and then to a quantum mechanically allowed excited state. Specifically the prior art does not show these two states of photons in PDT, in conjunction with the other method steps.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Daikuzono (5,050,597), Chen et al. (5,571,152; 5,445,608; 5,957960), Tan (5,217,455), Talmore (5,707,401), Kolobanov et al. (4,973,848), Woodburn et al. (5,775,339) all show PDT methods.

The examiner regrets that following the telephone restriction of February 2000, this case was misplaced in the office and the action was never sent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jocelyn D Ram whose telephone number is (703) 308-6392. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

JR
April 19, 2001

LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700